MAY 2 3 2001

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K004049**

Applicant information:

Date Prepared:	December 25th, 2000
Name:	**Optech, Inc.**
Address	6431 South Troy Circle Unit# E Englewood, CO 80111
Contact Person:	Mr. James Brooks President/CEO
Phone number:	(303) 708-1390
USA Consultant:	Med-Vice Consulting, Inc. Mr. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501
Email address:	mdalsing@gj.net

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear

Trade Name: **PolyVue ® Multifocal (polymacon) Soft Contact Lens for Daily Wear (clear and visibility tinted, fully cast-molded lens)**

Purpose of 510(k) Submission:

NEW DEVICE ~

Optech, Inc. proposes to market and sell in United States interstate commerce, a fully cast-molded soft contact lens of the (polymacon) soft contact lens material and made available in a multifocal product configuration. Data supporting substantial equivalency to the predicate device, performance, and safety & efficacy of the (polymacon) polymer is contained in this submission.

Equivalent Devices:

The **PolyVue ® Multifocal** (polymacon) Soft Contact Lens is substantially equivalent to the following predicate device:

Predicate device:

- "PolyVue 43" (ocufilcon A) K982110, manufactured by Optech, Inc.

Device Description:

The **PolyVue ® Multifocal** (polymacon) Soft Contact Lenses are hemispherical shells with molded spherical base curves and a molded front surface design consisting of four zones of non-linear multi-aspheric power progressions. The central zone is the patented accommodation zone that is created by a very small area of over magnification in the center of the pupil. The accommodation zone is blended into the distance zone by two zones of non-constant asphericity, which provides near, intermediate and distance vision. The **PolyVue ® Multifocal** soft contact lens is fabricated from a nonionic polymer.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2- Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. The lenses are available clear or with a visibility handling tint. The lenses are tinted for visibility purposes from edge to edge using one or a combination of one or more of the following 'listed' color additives:

Phthalocyanine blue (21 CFR § 74.3045)
Phthalocyanine green (21 CFR § 73.3124)

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of the lens are:

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 90%
Light Transmission (tinted)	greater than 90%
Water Content	38 % ± 2%
Oxygen Permeability	8.4×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The **PolyVue ® Multifocal** (polymacon) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or with a visibility handling tint.

Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

Pre-Clinical Performance Data:

The following pre-clinical performance data on the **PolyVue ® Multifocal** soft contact is presented in the submission.

- Cytotoxicity Test
- Systemic Injection Test
- Eye Irritation Test
- Compatibility Testing
- Preservative Uptake and Release
- Leachability of Color Additives and Residual Monomers

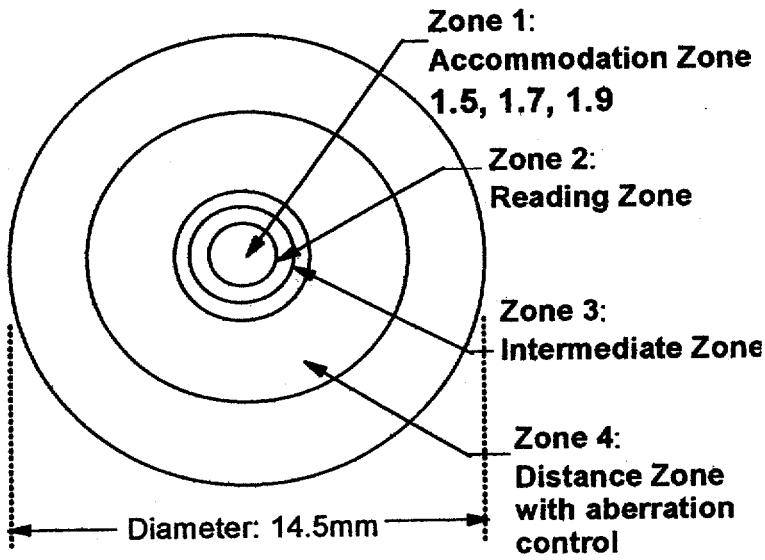
These studies demonstrate that the material is non-toxic, compatible with standard lens care regimens and that the residual monomers and color additive leachability is within acceptable limits.

Concerning compatibility testing, the recommended lens care products (cleaning, rinsing and disinfection) have been approved for use with lenses of the same lens group. Therefore, no additional compatibility testing is included.

With regard to preservative uptake and release studies, since the subject contact lens material (polymacon) is not a new and/or modified lens material, no additional studies need be conducted.

Optech, Inc. has also included in this submission the results of 10 multifocal lenses manufactured via the cast-molding process to a variety of prescribed specifications to verify ability of the manufacturer to make these lenses.

Design Specifications & Parameters Available:



PolyVue ® Multifocal ~ cast molded lens

Design:	**Aspheric near center add**
Base Curve:	**8.4mm & 8.60mm**
Diameter:	**14.0mm & 14.50mm**
Center Thickness:	**0.04mm at –4.00D**
Spherical Power:	**+4.00D to –12.00D (0.25 steps)**
Addition Power:	**Continuous to +2.50D LO**
	Continuous to +3.25D HI
Optical Add Zone:	**1.5, 1.7, 1.9**

Substantial Equivalence:

The **PolyVue ® Multifocal** Soft Contact Lens will be manufactured and packaged according to specified process controls and a CGMP quality assurance program currently in place. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **PolyVue ® Multifocal** material is equivalent to the predicate device identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies between the **PolyVue ® Multifocal** Soft Contact Lens and the substantial equivalent predicate device.

Substantial Equivalence Matrix

Substantial Equivalency	PolyVue 43 ® (ocufilcon A) Multifocal [predicate device]	PolyVue ® (polymacon) Multifocal [new device]
Manufacturer	Optech, Inc.	Optech, Inc.
INDICATION	The PolyVue 43 (ocufilcon A) multifocal Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia), presbyopia in aphakic and not aphakic persons with non-diseased eyes. The lens is available clear or visibility tinted.	The PolyVue ® Multifocal (polymacon) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or visibility tinted.
INTENDED USE	Daily Wear, Soft (hydrophilic) Contact Lens	Daily Wear, Soft (hydrophilic) Contact Lens
Actions	When placed on the cornea acts as a refracting media to focus light rays on the retina.	When placed on the cornea acts as a refracting media to focus light rays on the retina.
Manufacturing Method	Lathe-cut	Fully cast-molded
USAN name Material name	ocufilcon A	polymacon
Water Content (%)	43%	38%
Toxicology	Non-Toxic	Non-Toxic
Power profile	Indentical to the fully cast-molded lens as displayed by Visionix measurements.	Indentical to the lathe-cut lens as displayed by Visionix measurements.
Burst Strength	35.2 PSI	33.5 PSI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Mr. Martin Dalsing
Consultant for Optech, Inc.
c/o Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K004049
Trade Name: PolyVue® Multifocal (polymacon) Soft Contact Lens for Daily Wear
(clear and visibility tinted, fully cast-molded)
Regulatory Class: II
Product Code: LPL
Dated: April 11, 2001
Received: April 16, 2001

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **PolyVue ® Multifocal (polymacon) Soft Contact Lens for Daily Wear (clear and visibility tinted, fully cast-molded)**

INDICATIONS FOR USE:

The **PolyVue ® Multifocal** (polymacon) Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes with myopia or hyperopia and are presbyopic. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or visibility tinted.

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(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K004049

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)